510(k) Summary

Device Trade Name:	EXp Tibial Inserts and Patellar Components for StelKast's Proven Gen-Flex™ Total Knee System
Manufacturer:	StelKast, Inc. 200 Hidden Valley Road McMurray, PA 15317
Contact:	Mr. David Stumpo Vice President of Product Development Phone: 724.731.2208 Fax: 724.941.5987 dstumpo@stelkast.com
Prepared by:	Musculoskeletal Clinical Regulatory Advisers, LLC 1331 H Street NW, 12th Floor Washington, DC 20005 Phone: (202) 552-5800 Fax: (202) 552-5798
Date Prepared:	June 30, 2013
Classification:	21 CFR 888.3560, Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Class:	II
Product Codes:	JWH, OIY

AUG 0 5 2013

Indications For Use:
The Proven Gen-Flex™ Total Knee System is intended for:

1. Total knee replacement due to osteoarthritis, osteonecrosis, rheumatoid arthritis, and/or post-traumatic degenerative problems.

2. Revision of failed previous reconstructions where sufficient bone stock and soft tissue integrity are present.

The device is intended for cemented use only.

Device Description:
The EXp Tibial Inserts and Patellar Components are made of polyethylene to which Vitamin E has been blended. The tibial inserts are available in "Cruciate Retaining" (CR) and "Posterior

Stabilized" (PS) designs. The patellar components are available Single Peg and Three Peg designs. These implants are part of the Proven Gen-Flex™ Total Knee System and will be used in conjunction with a femoral component and tibial baseplate in total knee arthroplasty.

Predicate Devices:
Comparative information presented in the 510(k) supports the substantial equivalence of the EXp Tibial Inserts and Patellar Components with respect to their intended use, design, materials, range of sizes, method of fixation, and performance.

This 510(k) demonstrates the substantial equivalence of the EXp Tibial Inserts and Patellar Components to the following predicate devices:

- StelKast Proven Cemented, Semi-Constrained Total Knee System (K980276)
- Stelkast Proven Knee System High Flexion Tibial Insert (K063211)
- Stelkast EXp Acetabular Liner (K094035)
- Biomet Vanguard® Complete Knee System (K113550)

Preclinical Testing:
Non-clinical testing was performed on the EXp Tibial Inserts to assess the interconnection mechanism between the insert and tibial baseplate, and the integrity of the tibial post on the posterior-stabilized design. The inserts were also subjected to knee simulator wear testing per ISO 14243-1; and oxidative stability testing per ASTM F2102, after aging per ASTM F2003 after 10 million cycles of knee simulator wear testing. The testing demonstrates that the EXp Tibial Inserts are substantially equivalent to legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

August 5, 2013

StelKast, Incorporated
% Mr. David Stumpo
Vice President of Product Development
200 Hidden Valley Road
McMurray, Pennsylvania 15317

Re: K122883
Trade/Device Name: EXp Tibial Inserts and Patellar Components for StelKast's Proven Gene-Flex™ Total Knee System
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JWH, OIY
Dated: July 25, 2013
Received: July 26, 2013

Dear Mr. Stumpo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith

For

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use

510(k) Number (if known): K122883

Device Name: EXp Tibial Inserts and Patellar Components for StelKast's Proven Gen-Flex™ Total Knee System

The Proven Gen-Flex™ Total Knee System is intended for:

1. Total knee replacement due to osteoarthritis, osteonecrosis, rheumatoid arthritis, and/or post-traumatic degenerative problems.

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The device is intended for cemented use only.

Prescription Use ___√___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.

Division of Orthopedic Devices